

**REMARKS**

In this Response, claims 62-69 are added. Therefore, after entry of this amendment which is respectfully requested, claims 8, 10-11 and 60-69 are all the claims pending in the application.

New claims 62 and 63 are supported by the specification at, for example, pages 8 and 9.

New claim 64 is supported by the specification, for example, at the paragraph bridging pages 9 and 10.

New claim 65 is supported by, for example, original claim 7.

New claim 66 is supported by, for example, original claim 5.

New claim 67 is supported by, for example, original claim 6.

New claim 68 is supported by, for example, original claim 7.

New claim 69 is supported by the specification, for example, at page 28.

New claim 70 is supported by, for example, claim 61.

New claims 71 and 72 are supported by the specification, for example, at page 38.

Applicants submit that no new matter has been added, and respectfully request that the Amendment be entered.

**I. Claim Rejections Under 35 U.S.C. § 112, 1st Paragraph**

At paragraph 2 of the Office Action, claims 8, 10, 60 and 61 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Specifically, the Examiner states that the specification only provides a written description of how

Amendment under 37 C.F.R. § 1.111  
USSN 09/869,142

to search and screen for the claimed invention, and that the specification does not provide a written description of all possible mutant microorganisms which convert any cyano group into any carboxyl group and are which are defective or reduced in converting any cyano group into any amide group. The Examiner further states that the specification only provides a written description of a single representative species, specifically, a *Rhodococcus* sp. SD826 (FERM BP-7305) strain.

Initially, Applicants respectfully remind the Examiner that claim 8 has previously been amended to recite microorganisms of the genus *Rhodococcus*, and therefore, Applicants are not claiming “any” microorganism with the recited properties as the Examiner maintains.

In addition, Applicants submit that the Examiner has applied a legally improper standard of the written description requirement as interpreted by the Patent Office and the Federal Circuit.

MPEP § 2163(II)(A)(3)(a)(ii) provides that:

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice..., reduction to drawings..., or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by combination of such identifying characteristics, sufficient to show that Applicant was in possession of the claimed genus....

(Emphasis added)

Applicants assert that the present specification provides an adequate written description of the claimed mutant microorganism of the genus *Rhodococcus*. The relevant characteristics of the mutant microorganism of the invention (i.e. claim 8) are: (1) a microorganism of the genus *Rhodococcus*, (2) a property of converting a cyano group into a carboxyl group, and (3) a property of being defective or reduced in the activity of converting a cyano group into an amide group. All three characteristics are sufficiently described in the specification such that one skilled in the art would understand that the inventors had possession of the claimed invention. Microorganisms of the genus *Rhodococcus* are known in the art and are described throughout the specification, for example, at pages 4, 5, 6, 9, 10. A property of converting a cyano group into a carboxyl group and a property of converting a cyano group into an amide group are practically described or discussed in some fashion on every page of the application.

Thus, Applicants submit that the specification provides more than an adequate written description of the claimed invention as this requirement has been interpreted by the Patent Office.

Second, the Federal Circuit has noted that the written description requirement has been applied in two situations. See *Moba v. Diamond Automation, Inc.*, 325 F.3d 1306 (Fed. Cir. 2003). First, the written description requirement has been applied to police priority of invention for claims added during prosecution of an application. *Id.* at 1319. Second, the written description requirement has been applied to original claims where the disclosure does not sufficiently describe the claimed subject matter. *Id.* at 1320. This

second application of the requirement, which is relevant to the Examiner's present written description rejection, is typically applied to nucleotide and amino acid sequence claims where such nucleotide and protein sequences are claimed functionally and without sufficient structural information such that one skilled in the art would understand that the inventor had possession of the claimed invention. *See Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997). Such a written description rejection is based on the fact that changes to DNA and protein sequences lead to unpredictable effects on protein activity.

Applicants assert that the Examiner has improperly applied the latter application of the written description requirement in the current case, as the subject matter of the present claims do not suffer from the unpredictability of functionally claimed DNA and protein molecules. Species of the genus *Rhodococcus* are well known in the art, and are well described in Applicants' specification (see, for example, pages 4-6, and 9-10). Further, Applicants describe, in-depth, the relevant biochemical properties of converting a cyano group into a carboxyl group and converting a cyano group into an amide group, and give numerous examples, such that one skilled in the art would understand what is being claimed and that Applicants' had possession of the claimed invention.

Thus, the Examiner has applied an improper standard of the written description requirement as this requirement has been interpreted by the Federal circuit.

In view of the above, Applicants respectfully request reconsideration and withdrawal of this rejection.

## II. Claim Rejections Under 35 U.S.C. § 102

At page 3 of the Office Action, claim 8 stands rejected under 35 U.S.C. § 102(a) as anticipated by Kato et al. Specifically, the Examiner contends that Kato et al. teach that upon heat treatment, *Rhodococcus* sp. strain YH3-3 contains a nitrile hydratase which is reduced to 55% activity, and in absence of facts to the contrary, inherently has an active nitrilase which converts a cyano group into a carboxyl group.

First, with regard to the putative active nitrilase of Kato's *Rhodococcus* sp. Strain YH-3, Applicants respectfully remind the Examiner that Applicants had explained in the Response filed October 9, 2003, based on the evidence presented by Kato et al., that the heat-treated cells of Kato do not convert a cyano group into a carboxyl group as the Examiner suggests. Specifically, Applicants had explained that the acetone-dried and heat-treated cells in Kato contain neither the activity of converting a cyano group into a carboxyl group (nitrilase activity), nor a fully active nitrile hydratase that converts a cyano group into an amide group. As shown in Kato *et al.* Figure 2, synthesized 3-cyanopyridine was not degraded in either acetone-dried cells or heat-treated cells of *Rhodococcus* sp. strain YH-3. These acetone-dried cells and heat-treated cells can have neither an active nitrile hydratase nor an active nitrilase, since both nitrile hydratase and nitrilase degrade 3-cyanopyridine, and such was not degraded in Kato Figure 2, once the yield of 3-cyanopyridine reached maximum (the period of 120-180 min.).

Applicants assert that the Examiner has not responded to these arguments, and Applicants again request reconsideration and withdrawal of this rejection.

In addition, Applicants assert that the present claims recite a mutant strain of a microorganism belonging to the genus *Rhodococcus*. On the other hand, the YH-3 strain of Kato

Amendment under 37 C.F.R. § 1.111  
USSN 09/869,142

was "isolated from soil" (Kato, page 250, first column, fourth paragraph). Therefore, since YH-3 of Kato was not genetically manipulated in any fashion, Kato does not teach a mutant microorganism of the genus *Rhodococcus* as currently claimed.

Accordingly, Applicants request reconsideration and withdrawal of this rejection.

### III. Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

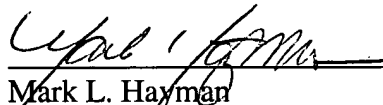
Respectfully submitted,

SUGHRUE MION, PLLC  
Telephone: (202) 293-7060  
Facsimile: (202) 293-7860

WASHINGTON OFFICE

**23373**

CUSTOMER NUMBER

  
Mark L. Hayman  
Registration No. 51,793

Date: June 9, 2004